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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,850	05/11/2001	Kohshi Ueno	0425-0838P	7071

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BIRCH STEWART KOLASCH & BIRCH  
PO BOX 747  
FALLS CHURCH, VA 22040-0747

EXAMINER

PATEL, SUDHAKER B

ART UNIT	PAPER NUMBER
1624	2

DATE MAILED: 02/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. 09/852,850	Applicant(s) Kohshi Ueno et al
Examiner Sudhaker Patel	Art Unit 1624

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on May 11, 2001

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 835 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-11 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-11 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15)  Notice of References Cited (PTO-892)

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1

18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

19)  Notice of Informal Patent Application (PTO-152)

20)  Other: \_\_\_\_\_

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## **DETAILED ACTION**

The claims in this application are the claims 1-11.

As applicants are aware the parent application Sr. No. 09509778 filed 3/31/2000 had following restriction/election requirements:

### **I. Restriction/Election:**

**Group I**, claim(s) 1-13 (in part), drawn to compounds, simple composition, and a method of use of Formula (I) wherein A = Phenyl; B = Aryl (i.e. Non-heterocycle).

**Group II**, claim(s) 1-13 (in part), drawn to compounds, simple composition, and a method of use of Formula (I) wherein A = Pyridine; B = Non-Heterocycle, and Heterocycle only involving imidazole, piperidine, furan, thiene , pyran. And ben-fused structures.

**Group III**, claim(s) 1-13(in part), drawn to compounds, simple composition, and a method of use of Formula (I) wherein A = Thiophene, furan; B = Heterocycle having 6-membered ring e.g. morpholine, 1,4; 1,3; diazine/diazine etc.

**Group IV**, claim(s) 1-13 (in part), drawn to compounds, simple composition, and a method of use of Formula (I) wherein A = Heterocycle or Non-Heterocycle; B = Heterocycle with 7-members and larger.

**Group V**, claim(s) 1-13 (in part), drawn to compounds not included in above groups.

Applicants are required to elect one of the above groups, and also a species representing the elected group in reply to office action.

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Applicants had elected invention of Group III for the parent application Sr. No. 09509778 filed 3/31/00 now allowed U.S.P. 6340759.

A telephone call was made to Mr. R. C. Stewart on 9/6/01 to request an oral election to the above restriction requirement, and applicants elected invention of Group I claim(s) 1-11 (in part), drawn to compounds, simple composition, and a method of use of Formula (I) wherein A = Phenyl; B = Aryl (= Non-heterocycle), namely isoquinoline nucleus with subsstituents R1, R2, R3, and -(CH<sub>2</sub>)<sub>n</sub>-B. Affirmation of this election by the applicants must be done in response to this action. Since claims 1-11 link with other inventions, the instant application will be examined bearing in mind the subject matter of Group I as elected by the applicants only. Applicants are urged to limit the scope of the claims to the elected subject matter and also recheck the claim dependency in reply to this Office Action.

*Specification*

1. The abstract of the disclosure is objected to because as presented it includes many figures and is provided on two separate pages. It should occupy only one page. Correction is required. See MPEP § 608.01(b).
2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.
3. The following title is suggested: ISOQUINOLINE DERIVATIVES

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***Claim Rejections - 35 U.S.C. § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second para. as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention.

A). Claim 1 and claims dependent on this claim recite compounds and their “hydrated”. It is not very clear as to nature of the hydrated. Is it mono-, di-, sesqui-hydrate? Clarification is requested..

B). Claims 8- 11 recite an agent or a method for “treating, ameliorating or preventing diseases”. It is not very clear as to what applicants want to accomplish. Does “treating include curing”? Deletion of preventing is suggested.

C). Claim 8 recites “diseasesagainstwhichserotoninantagonismis efficacious”. It is suggested to separate the words by way of necessary correction(s).

D). Claim 11 has the same problem as stated in C). Above. Correction is requested.

E). Claims 7,8,9, 10 recite “ medicinal composition, an agent, or a muscle relaxant respectively”. It is not very clear as to what applicants wish to claim. Is a pharmaceutical composition excluded from above terms?

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8,9, 11 are rejected under 35 U.S.C. 112 first paragraph, as containing subject matter which was no described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not give any guidance as to the full range of spastic paralysis/disease or myotonia which could be treated or ameliorated or prevented using instantly claimed step of administering a pharmaceutically effective dose of compound(s) of claim 1, its pharmaceutically acceptable salt or hydrates thereof to a patient.

In evaluating the enablement question, several factors are to be considered. In re Wands, 8 USPQ 2d 1400 (Fed. Cir. 1988); Ex parte Forman, 230 USPQ 546. The factors include:

- (1). The nature of invention,
- (2). the state of prior art,
- (3). the predictability or lack thereof in the art,
- (4). the amount of direction or guidance present,
- (5). the presence or absence of working examples,
- (6). the breadth of the claims,
- (7). the quantity of experimentation needed, and
- (8). the level of the skill in the art.

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In the instant case, Applicants are claiming a method or an agent for treating, ameliorating or preventing diseases against which serotonin antagonism is efficacious. The nature of the pharmaceutical art(s) is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any medicinal or therapeutic regimen on its face. The instant specification does not give any guidance as to the full range of serotonin effected diseases which could be treated or ameliorated or prevented using the instantly claimed step or process. In order to practice the claimed invention, one skilled in the art would have to speculate which disease could be treated or ameliorated or prevented using the claimed isoquinoline derivatives found in the instant claims. The number of possible diseases embraced by the claims would impose undue experimentation on the skilled art worker. Therefore, the broad terminology is not enabled because the metes and bounds of the diseases which could be treated or ameliorated or prevented by using the derivatives found in the instant claims and the same can not be ascertained.

Applicants' attention is drawn to MPEP 806.05(h) which provides for one method of use to be examined with the elected compounds. A broad disclosure of utility as in the cited claims 11 can not be deemed in compliance with 35 U.S.C. 112, first paragraph.

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This requirement of one specific utility is also in compliance with 37 CFR 1.475 the unity of Invention Practice in International Applications and National Phase Applications under U.S.C. 371, and PCT Rule 13.2.

Therefore, applicants should limit the method claim to a sole “specific utility”.

### ***Conclusion***

### ***Allowable Subject Matter***

6. The following is a statement of reasons for the indication of allowable subject matter:

Claims(in part) 1,6 related to compounds if limited to elected invention of Group I only are allowable provided applicants can attend various issued raised in the above mentioned rejection.

The closest prior art reference Simpson et al (U.S.P. 3857944) teaches making of 1-piperazinoisoquinolines with 2-position(= R2 of ref.) as H/lower alkyl/alkoxy/ only, whereas in the instantly claimed compounds the 2-position is specifically occupied by-(CH<sub>2</sub>)<sub>n</sub>-B wherein B is aryl, or heteroaryl which could be either unsubstituted or substituted by other variables. Thus, the ref. ‘944 differs from the instantly claimed invention by not having 2-position specifically occupied by ether phenyl or heteroaryl group. There is no teaching or indication of any kind to motivate anybody for arriving at the instantly claimed structure.

Therefore, the instantly claimed compounds deem to be novel and patentably distinct.

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This application has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is, therefore, requested in promptly correcting any errors of which they may become aware in the specification.

Applicants are advised to provide the information related to instant application &/or similar &/or presently pending local or international applications, if any, related to the subject matter included in the instant application to avoid various issues arising out of question of either double patenting &/or priority claims and other related matters.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker Patel, D.Sc. Tech. whose telephone number is (703) 308 4709.

The examiner can normally be reached on Monday thru' Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah can be reached at (703) 308 4716.

A facsimile center has been established for Group 1600. The hours of operation Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

Any inquiry of general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 1235.

*Mukund J. Shah*

**Mukund Shah**

**Supervisory Patent Examiner**

*sp* *SJShah*

February 18 , 2002.

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